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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,500	12/05/2005	Takashi Suzuki	OKA-0230	1582

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
07/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,500	SUZUKI ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-22* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-18 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/28/09 has been entered.

In the amendment filed on 5/28/09, Applicants switched the elected invention from Group I to Group III, and maintained cultured mammalian cell derived from gonad as the elected species without traverse.

Accordingly, claim 19 was withdrawn from further consideration because it is directed to a non-elected species.

Claims 11-18 and 20-22 are pending in the present application, and they are examined on the merits herein with the above elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-18 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Chatterjee et al. (US 200/20168706).

It is noted that the instant claims are directed to a method for cell-free protein synthesis comprising a **single step of using a cultured mammalian cell extract liquid to conduct a cell-free protein synthesis reaction**, wherein the cultured mammalian cell extract liquid was prepared by a particular preparation method comprising at least the step as recited in independent claim 11. The examiner interprets **"a cultured mammalian cell extract liquid" as a product-by-process** and also notes that the claimed method does not necessarily require all the steps of the preparation method. Additionally, a cultured mammalian cell extract liquid obtained from the broad preparation method to be used in the cell-free protein synthesis method also does not necessarily contain a protease inhibitor as recited in claim 18.

Chatterjee et al disclose an in vitro peptide/protein synthesis comprising mixing RNA templates with at least cell extracts, and incubating the mixtures under conditions sufficient to produce one or more peptides or proteins encoded by all or a portion of the templates (see at least Summary of the Invention, particularly paragraphs 43-45 and 62-63), wherein cell extracts are derived from prokaryotic or eukaryotic cells or cell lines (paragraphs 78-79), including mammalian cells such as NIH3T3, CHO, COS, C127, VERO, BHK, HeLa, 293 and that cell extracts can be prepared by any method used in the art that maintains the integrity of the transcription/translation system or if the process damages one or more component necessary for any stage of transcription/translation , the damaged component can be replaced or substituted for after the extraction preparation (paragraphs 100, 102). Chatterjee et al also teach that an exemplified incubation mixture contains K-glutamate, $Mg(OAc)_2$, DTT and

Hepes/KOH at pH8.2 (paragraph 104) and the reactions were carried out at 37^0C (paragraphs 128, 135). It is also noted in an exemplification, harvested cell pellet was frozen, thawed and resuspended in an extract buffer prior to sonication and clarification by centrifugation (paragraph 122).

Accordingly, the teachings of Chatterjee et al meet all the limitation of the claims as written. Therefore, the reference anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (US 200/20168706) in view of Reiter et al. (US 6,475,725).

It is noted that the instant claims are directed to a method for cell-free protein synthesis comprising a **single step of using a cultured mammalian cell extract liquid to conduct a cell-free protein synthesis reaction**, wherein the cultured mammalian cell extract liquid was prepared by a particular preparation method comprising at least the step as recited in independent claim 11. The examiner interprets **"a cultured mammalian cell extract liquid" as a product-by-process** and also notes that the claimed method does not necessarily require all the steps of the preparation method.

Chatterjee et al disclose an in vitro peptide/protein synthesis comprising mixing RNA templates with at least cell extracts, and incubating the mixtures under conditions sufficient to produce one or more peptides or proteins encoded by all or a portion of the templates (see at least Summary of the Invention, particularly paragraphs 43-45 and 62-63), wherein cell extracts are derived from prokaryotic or eukaryotic cells or cell lines (paragraphs 78-79), including mammalian cells such as NIH3T3, CHO, COS, C127, VERO, BHK, HeLa, 293 and that cell extracts can be prepared by any method used in the art that maintains the integrity of the transcription/translation system or if the process damages one or more component necessary for any stage of transcription/translation , the damaged component can be replaced or substituted for after the extraction preparation (paragraphs 100, 102). Chatterjee et al also teach that an exemplified incubation mixture contains K-glutamate, $Mg(OAc)_2$, DTT and Hepes/KOH at pH8.2 (paragraph 104) and the reactions were carried out at 37^0C (paragraphs 128, 135). It is also noted in an exemplification, harvested cell pellet was

frozen, thawed and resuspended in an extract buffer prior to sonication and clarification by centrifugation (paragraph 122).

Chatterjee et al do not teach specifically the use of CHO derived from CHO K1-SFM. It is also noted that the instant application provides no limiting definition of a CHO K1-SFM cell. Therefore, the limitation is construed based on its plain meaning in the art as a CHO K1 cell adapted for growth in serum free medium.

At the effective filing date of the present application, Reiter et al already disclosed production of recombinant proteins in CHO cells adapted for growth in serum- and protein-free medium (see throughout, especially col. 6, line 31 through col. 7, line 15) and taught that CHO-K1 cells as a preferred cell type for preparing recombinant proteins (col. 6, line 49).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made also using the CHO-K1-SFM cell of Reiter et al for preparation of a cell extract to be used in the in vitro peptide/protein synthesis system of Chatterjee et al. In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized "the need for caution in granting a patent based on a combination of elements found in the prior art," (*Id.* At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on it precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."(*Id.* At 1395.).

In the instant case, the method of Chatterjee et al differs from the method presently claimed only in the substitution of CHO cell for the CHO K1-SFM required by the instant claim. However, the teachings of Reiter et al demonstrate that CHO K1-SFM cells and their use in the expression of recombinant proteins were known in the art at the time of the present invention was made. An ordinary skill in the art could have selected CHO K1-SFM of Reiter et al for preparation of a cell extract to be used in the in vitro peptide/protein synthesis system of Chatterjee et al. with a predictable outcome since Chatterjee et al teach explicitly that cell extracts can be derived from any prokaryotic or eukaryotic cells or cell lines.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. WO 00/50586 (IDS) disclosed that protease inhibitors are optionally added in an extraction buffer containing Hepes, KOAc, Mg(OAc)2, DTT for the preparation of cell-free extracts from HeLa cells to be used in a cell-free translation system (see at least example 4).

2. Arakaki et al (US 6,103,489; IDS) disclosed at least that **Xenopus egg extract to be used in cell-free translation system is stable to freezing at -70 ^{o}C and to repeated freezing and thawing** (col. 4, lines 28-29).

3. At the effective filing date of the present application, at least Elliott et al (US 5,716,985; Cited previously) and Marusic et al. (Croatian Medical Journal 33:207-212, 1992; IDS) already taught **lysis of mammalian cells by freezing-thawing in a lysis buffer**.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN/

Primary Examiner, Art Unit 1633